

An aerial photograph of Los Angeles, California, showing the city skyline with numerous skyscrapers in the background and the UCLA campus in the foreground. The campus features several large, multi-story buildings, green spaces, and a parking lot. A semi-transparent white box is overlaid on the left side of the image, containing the text "OHRPP UPDATES" and "AUGUST 8, 2024".

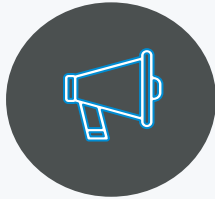
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# OHRPP UPDATES

AUGUST 8, 2024

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# OHRPP UPDATES



**GO LIVE CONFIRMED:**  
**Monday, September 9, 2024**



As a reminder, UCLA is transitioning from webIRB to [BruinIRB](#) as our IRB submission system.

### Why is this transition necessary:

- webIRB is a highly customized application that requires significant IT resources to manage.
  - webIRB application version is no longer supported by the vendor.
- BruinIRB utilizes a streamlined application and workflow.
  - Simplifies submissions by focusing on the upload of a scientific protocol and/or Human Subject protocol templates designed to obtain the information required for the IRB to make regulatory determinations.
- BruinIRB offers a streamlined user interface.



DATE	Key Event
August 9, 2024	<b>Updated OHRPP Website</b> Launched to include <a href="#">BruinIRB Resource Library</a>
September 7, 2024 8:00 am – September 9, 2024 8:00 am <b>*webIRB and BruinIRB unavailable for use*</b>	<b>Migration of legacy studies</b> (approved studies with no pending submissions). <ul style="list-style-type: none"><li>- All Full Board studies</li><li>- Begin expedited studies</li><li>- Migration to continue weekly until all legacy and in-flight studies established in BruinIRB</li><li>- Migration of all legacy studies anticipated to be completed by September 30, 2024.</li></ul>
<b>September 9, 2024 – BruinIRB Go Live</b>	<b>All New studies must be submitted in BruinIRB.</b> webIRB closed to creation of new studies.  <b>Follow on submissions (amendment, continuing review, PARs) for migrated studies</b> must submitted in BruinIRB.  Submissions “in flight” will be finalized in webIRB before being migrated to BruinIRB.
January 6, 2025	BruinIRB used for majority of IRB submissions.



## MAJOR DIFFERENCES

- Protocol Requirement
- Agree to Participate Requirement

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# IRB PROTOCOL TEMPLATES

- Every new study submission will require the upload of a study protocol
  - Industry-sponsor protocol
  - Scientific protocol submitted to funding source
  - Upload of grant alone will not address protocol requirement
- New OHRP Protocol Templates
  - [Biomedical Research Template](#)
  - [Behavioral Research Template](#)
  - [Secondary Analysis Template](#)
- IRB Supplements to Address Special Populations and other Regulatory Requirements
  - [Adults Not Able to Consent](#)
  - [Children](#)
  - [Pregnancy and Neonates](#)
  - [Prisoners](#)
  - [Wards](#)
  - [Waivers/alterations to the requirement for informed consent](#)
  - [HIPAA-covered Research](#)



### BruinIRB Protocol Templates and IRB Supplements

BruinIRB relies on the upload of a protocol document to address much of the information required by the IRB to address criteria for IRB review. To assist in the new protocol requirement, OHRPP has created protocol templates that can be used for each submission.

[IRB Prot.](#) [IRB Expedited](#) [IRB OHRPP](#)

#### Protocol Templates

- Biomedical research
- Socio-behavioral/educational research - subject contact
- No human subject contact research (records, data, specimen analysis)
- **Reliance studies - please submit the protocol that is being used at all sites**
- Emergency Use
- Humanitarian Use Device
- Right to Try
- **Expanded Access - Please see OHRPP Guidance and Procedures, Use of Drugs and Biologics in Clinical Research and Treatment or OHRPP Guidance and Procedures, Use of Devices in Clinical Research and Treatment for required sponsor or FDA documents that will serve as a protocol.**

Note: These protocol templates are also available within BruinIRB Library.

#### IRB Protocol Supplements

In some cases, the protocol may not address issues specific to human subject protections and so it may be necessary to complete an IRB protocol supplement. Supplements address specific research scenarios or address protections specific to certain populations.

- Adults Not Able to Consent
- Children
- HIPAA Covered Research
- Pregnancy and Neonates
- Prisoners
- Waivers
- Wards

#### BruinIRB Quick Guides

##### Investigator and Research Team Quick Guides

- Assign Primary Contact
- Change IRB
- Document Management
- Expanded Access Protocol
- Migrated webIRB Applications
- Obtain a BruinIRB Account
- Update Study Details
- Updating Your Contact Information and Profile in BruinIRB

##### IRB Members Quick Guides

Coming soon

##### OHRPP IRB Staff Quick Guides

- Assign Designated Reviewer (Non-Committee Review)
- Assign to Committee Review
- Assigning an Owner to a Submission
- Tip Sheet: BruinIRB "Edit Study" Activity for OHRPP Staff
- Updating Members and Committee Personnel

Basic Study Information

Study Funding Sources

Local (UCLA) Study Team Members

Study Scope

Local Research Locations

Local Site Documents

HIPAA (Study)

Clinical Research Form (Study)

4. \* What kind of study is this?

- Multi-site (Research study in which the same research procedures are performed at multiple sites) or Collaborative study (involves two or more research sites where each site is conducting a different part of a research protocol under the direction/control of the lead PI)
  - Single-site study (all research activities are conducted by one institution, UCLA only)
- [Clear](#)

5. \* Will an external IRB act as the IRB of record for this study?

- Yes
  - No
- [Clear](#)

6. \* Will your IRB act as the single IRB of record for other participating sites?

- Yes
  - No
- [Clear](#)

7. \* Local (UCLA) principal investigator:

IRBTST PL\_1 ...

PROF IN RES-HCOMP / MEDICINE-HEMATOLOGY-ONCOLOGY  
 PROF IN RES-FY / OBSTETRICS & GYNECOLOGY

8. Faculty Sponsor:

 ...

9. Below attach the scientific protocol AND/OR the human subjects protocol supplement applicable to your research. By protocol, we mean whatever document you have that provides the necessary information for IRB review (see help text):

[+ Add](#)

Document	Category	Date Modified	Document History
There are no items to display			

10. \* Select the IRB that you think best matches your research:

Name	Description
<input checked="" type="radio"/> Medical Institutional Review Board 1	MIRB1 reviews general and internal medicine, infectious diseases and ophthalmologic research.
<input type="radio"/> Medical Institutional Review Board 2	MIRB2 reviews oncology and hematology research.
<input type="radio"/> Medical Institutional Review Board 3	MIRB3 reviews neuroscience, neurology, psychiatric, drug abuse and dental research.
<input type="radio"/> North General Institutional Review Board	NGIRB reviews research from the College of Letters & Science and the Professional Schools.
<input type="radio"/> South General Institutional Review Board	SGIRB reviews social-behavioral research from the Schools of Public Health, Nursing, and Medicine.

[Clear](#)

11. \* Does the local principal investigator or their immediate family have a financial interest related to this research?

- Yes
  - No
- [Clear](#)



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# AGREE TO PARTICIPATE

- Every new study submission will require the agreement of each listed co-investigator and/or Faculty Sponsor before the PI may submit the protocol
- AGREE TO PARTICIPATE advises listed study co-investigators and/or Faculty Sponsors to:
  - Review and accept their proposed involvement
  - Disclose any potential conflicts of interests
- AGREEMENT must be received from all listed co-investigators and/or Faculty Sponsor before the PI may “Submit”

## Email notification sent to study team member when added to a study:

### Sign Off Required - Agree to Participate

Link: [IRB-24-0171](#)  
PI: Joe Bruin  
FS: Test Faculty Sponsor  
Primary Contact: Joe Bruin  
Title: Test Study  
Short Title: Agree to Participate Test Study

The above-referenced application has been drafted in BruinIRB and requires you to agree to participate before it can be submitted to the IRB. Please use the above link to go to the study workspace or use the below button to provide your decision:

Please contact the Principal Investigator (PI) or Primary Contact if you have any questions about your proposed involvement in this project (include email addresses). You may also decline to participate by selecting "No" in the Agree to Participate activity.

Please note, delays to signing off will cause delays for the study submission.

If there are any additional questions, please contact OHRPP at [ohrpp@research.ucla.edu](mailto:ohrpp@research.ucla.edu) or 310-825-5344.

Within the study workspace, study personnel will click on the Agree to Participate button to complete the required action:


### Next Steps

[Edit Study](#)


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[Printer Version](#)


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 [Assign Primary Contact](#)

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 [Manage Guest List](#)

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 [Agree to Participate](#)

## Agree to Participate – Key Personnel

Test Study Team Member

You have been selected as a member of the research team for " Test Study " ( IRB-24-0176 ). Note: If your name is not listed above, please log out of BruinIRB from your device and sign in again using your login credentials.

### 1. Please provide your assurances by selecting Yes below.

As a member of the Key Personnel, I assure the following:


- The information provided in this application is correct and complete.
- I will comply with all federal laws, state laws, and UCLA policies that apply to this study.
- I will comply with all OHRP, FDA, and UCLA reporting requirements, including serious and unexpected adverse events.
- I will disclose any of my own or any individual conflicts of interest related to the sponsor.
- I agree to participate in this project and I understand my responsibilities as part of the research team.

\* Do you agree to participate in this study?

Yes  No [Clear](#)

Note: Selecting No then clicking OK will send an email notification to the PI and other members of the study team requesting that they remove you from the list of proposed research team members.

### 2. Conflict of Interest Disclosure

\* Do you or your immediate family have a financial interest related to this research? 

Yes  No [Clear](#)

Agree to Participate pop-up:

A tab in the study workspace, will provide up to date status on each team member's Agree to Participate activity, Pending (no responses to Agree to Participate yet):



History	Funding	Contacts	Documents	Reviews	Snapshots	Agree to Participate
<b>Faculty Sponsor</b>						
<b>Name</b>		<b>Agree to Participate?</b>		<b>Date Agreed/Disagreed to Participate</b>		
Test Faculty Sponsor		Pending		Pending		
<b>Study Team Members</b>						
<b>Name</b>		<b>Agree to Participate?</b>		<b>Date Agreed/Disagreed to Participate</b>		
Test Study Team Member		Pending		Pending		

Once all team members have addressed the requirement, the PI is free to submit the study:



History	Funding	Contacts	Documents	Reviews	Agree to Participate	...
<b>Faculty Sponsor</b>						
Name	Agree to Participate?	Date Agreed/Disagreed to Participate				
Test Faculty Sponsor	Yes	8/7/2024				
<b>Study Team Members</b>						
Name	Agree to Participate?	Date Agreed/Disagreed to Participate				
Test Study Team Member	Yes	8/7/2024				

**Upon completion of all required agreements, the PI, Primary contact and Proxy will be notified by email.**



**UCLA**  
Research Administration

University of California Los Angeles  
10889 Wilshire Blvd, Suite 830  
Los Angeles, CA 90095-1406  
<https://ohrpp.research.ucla.edu/>

(310) 825-5344  
[ohrpp@research.ucla.edu](mailto:ohrpp@research.ucla.edu)

### **All Listed Co-Investigators Have Agreed to Participate**

Link: [IRB-24-0171](#)  
PI: Joe Bruin  
FS: Test Faculty Sponsor  
Primary Contact: Joe Bruin  
Title: Test Study  
Short Title: Agree to Participate Test Study

The above-referenced application has been updated in BruinIRB to reflect that all listed co-investigators have agreed to participate. Please use the above link to go to the study workspace and review the updated information and SUBMIT the application for IRB review.

Should the PI attempt to submit before all study team members have agreed, the following error message will display when clicking on the “Submit” activity.

This message will also display if someone indicated “No” to agreeing:

**Submit**

Could not execute the Submit activity due to one or more errors:

The PI, FS (if applicable), and all key personnel are required to agree to participate on the study prior to being submitted to the IRB. To locate who still needs to complete this activity, please view the study history or the “Agree to Participate” tab in the study workspace.

## OHRPP LEARN AT LUNCH

### *BruinIRB's "Agree to Participate" function*

Presented by Rebecca Flores Stella, OHRPP

This session will cover a new function for key personnel rolling out with the transition to BruinIRB.

Date: **Thursday, August 22, 2024**

Time: **Noon-1pm**

Location: **Zoom** ([Register](#) for this meeting)

# OHRPP LEARN AT LUNCH

## *“How to Submit New Studies in BruinIRB” (live repeat)*

Presented by OHRPP BruinIRB Transition Team

This session will discuss how to submit a new application for IRB/OHRPP review in BruinIRB.

Date: **Wednesday August 21, 2024**

Time: **Noon-1pm**

Location: **Zoom** ([Register](#) for this meeting)

# OHRPP LEARN AT LUNCH – RECORDINGS AVAILABLE

Date Presented	Presentation	YouTube Link
Wednesday May 22, 2024	Learn at Lunch: BruinIRB Phase 2 Roll-out Timeline	<a href="#">Recording Available</a>
Thursday June 6, 2024	Learn at Lunch: BruinIRB Protocol Uploads	<a href="#">Recording Available</a>
Tuesday June 25, 2024	Learn at Lunch: Migration of Existing Studies from webIRB to BruinIRB	<a href="#">Recording Available</a>
Tuesday July 9, 2024	Learn at Lunch: CRAMs and AMs in BruinIRB	<a href="#">Recording Available</a>
Wednesday July 24, 2024	Learn at Lunch: How to Submit New Studies in BruinIRB	<a href="#">Recording Available</a>

# OHRPP ZOOM DROP-IN

Quality Improvement Unit staff hosts half-hour open Q/A sessions every other week to answer your OHRPP-related questions

[Register once](#) to join any session

## Upcoming Office Hours:

- August 15, 2024, at 2pm
- August 29, 2024, at 2pm

# OHRPP CONTACT INFORMATION

Presenter Rebecca Flores Stella: [rebecca.stella@research.ucla.edu](mailto:rebecca.stella@research.ucla.edu)

Requests for trainings: [ohrppeqi@research.ucla.edu](mailto:ohrppeqi@research.ucla.edu)

Technical assistance for BruinIRB: [BruinIRB@research.ucla.edu](mailto:BruinIRB@research.ucla.edu)

Requests for specific study consultations:

- For studies already submitted: the OHRPP staff assigned to your protocol or the administrator for the committee to which your study has been assigned
- For studies not yet submitted:

<https://ohrpp.research.ucla.edu/ohrpp-staff-consults/>